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Qingbo Li

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MCQUAIDE BLASKO
811 UNIVERSITY DRIVE
STATE COLLEGE, PA 16801

EXAMINER

OLSEN, KAJ K

ART UNIT

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1795

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,558	Applicant(s) LI ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-22 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4-8, 14-20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Karger et al (USP 5,633,129).

3. With respect to claim 1, Karger discloses a method of separating a first sample comprising nucleic acids (col. 2, ll. 19-21), the method comprising: providing a matrix that is essentially free of denaturing agents (col. 5, ll. 50-52); raising a temperature of a first portion of the matrix to a temperature of at least 80 °C (col. 5, ll. 56-63); subjecting the nucleic acids to electrophoresis through at least the first portion of the matrix (col. 12, l. 49- col. 13, l. 22); and deliberately leaving a second portion of the matrix cool (col. 13, ll. 54-58) to less than about 30 °C (col. 13, ll. 64-66 and col. 13, ll. 54-58), the nucleic acids migrating through the second portion after they have first migrated through the first portion (col. 14, ll. 54-59). Because this second portion of the matrix is deliberately left cool, it reads on the claimed step “deliberately cooling” giving the claim language its broadest reasonable interpretation. See also the alternative rejection below.

4. With respect to claim 2, see col. 13, ll. 64-66.

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5. With respect to claim 4, Karger relies on “ambient temperature”, which is below 25 °C because Karger defines “above ambient temperature” as being at least 24 °C. See col. 13, ll. 50-66.
6. With respect to claim 5, see col. 5, ll. 50-52.
7. With respect to claims 6 and 7, Karger utilized the same matrix material for an additional sample including approximately 30 runs. See col. 19, l. 61-col. 20, l. 17. Although Karger ultimately teaches against reusing the matrix for second and subsequent runs does not alter the fact that Karger explicitly demonstrated the claimed use of the matrix for subsequent measurements.
8. With respect to claim 8, see col. 13, ll. 61-66.
9. With respect to claims 14-18, see the discussion of claims 1, 2, 4, and 6 above.
10. With respect to claim 19, see col. 23, ll. 30-34.
11. With respect to claim 20 (those limitations not discussed above), Karger discloses that the detector can be placed at the terminus remote from the loading point of the channel. See col. 15, ll. 13-16. Because the second portion of the capillary would read on any of the 8 cm of capillary that is not being cooled (col. 13, ll. 56-60), then the terminus of the capillary can be construed as being downstream of this cooled portion of the capillary.
12. With respect to claim 22, see the discussion of claims 1 and 6 above.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 2, 4-8, 17, 18, 20, and 22 in the alternative are rejected under 35 U.S.C. 103(a) as being unpatentable over Karger in view of Hjerten (USP 4,906,344). Hjerten is being cited and relied on for the first time with this office action.

15. In the rejection above, the examiner maintained that deliberately leaving the ends of the capillary unheated while the remainder of the capillary get heated to an elevated temperature constituted a deliberate cooling of a portion of the matrix (see rejection above). However, even if the examiner were to interpret this claimed process as requiring explicit autonomous structure for the purpose of cooling the capillary, it is noted that it is well known in the art to either heat or cool a capillary or portions of a capillary in order to precisely control the temperature of the measurement. One particular example of such a system is Hjerten, which teaches a means for controlling a temperature of the capillary to be either hotter or cooler dependent on the experimental needs. See fig. 1, abstract and col. 4, ll. 56-62. Because Karger explicitly indicated that they do not want the ends of the capillary to be in the heated or denaturing zone (col. 13, ll. 54-60), then one possessing ordinary skill in the art at the time of the invention would have been motivated to utilize a cooling means, such as taught by Hjerten, for the ends of the capillary to ensure that residual heat from the denaturing zone doesn't eventually warm up the ends of the capillary via thermal transfer through the capillary itself. An active cooling means would ensure that "the beginning portion and opposite end portion of the column are not included in the denaturing zone" (Karger, col. 13, ll. 54-56).

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16. Claims 3, 9, 10, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karger (or Karger and Hjerten) in view of Demorest et al (USP 5,264,101) or Menchen et al (USP 5,290,418). Demorest and Menchen are being cited for the first time with this office action.

17. With respect to claims 3, 9, and 21 (those limitations not covered above), Karger (or Karger and Hjerten) set forth all the limitations of the claims, but did not explicitly recite the use of a linear copolymer comprising acrylamide and a secondary monomer. Karger relied instead on just linear polyacrylamide. See col. 20, ll. 10-17. Demorest teaches that acrylamide can be copolymerized with an additional charged monomer to create a polymer for capillary electrophoresis that is less susceptible to electroosmotic flow of the polymer in view of the charged monomer adhering to the oppositely charged capillary. See fig. 8; col. 4, ll. 47-53 and col. 12, ll. 44-60. Menchen teaches that linear copolymers can be made from a combination of hydrophilic monomers such as acrylamide combined with hydrophobic monomers. See col. 7, ll. 14-29 and col. 8, ll. 23-39. Said additional of hydrophobic groups allows the polymer solution to aggregate (provide a high viscosity) without the need for cross-linking the polymer to itself. Menchen further provides a matrix to be better tailored to provide for high resolution screening of biomolecules for a defined molecular size range. See col. 3, ll. 43-59. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize either the teaching of Demorest or Menchen and provide a secondary monomer for the acrylamide monomer of Karger so as to reduce the electroosmotic flow of the polymer or to better tailor the resolution and aggregate properties of the polymer for the biomolecules undergoing electrophoresis.

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18. With respect to claim 10, Demorest teaches the use of vinyl pyridine (col. 13, ll. 54-66).

Allowable Subject Matter

19. Claims 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. Claim 13 is allowed.

21. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 11 and 12, the prior art does not disclose nor render obvious all the cumulative limitations of claim 9 where the secondary monomer is N,N-dimethylacrylamide.

With respect to claim 13, the prior art does not disclose nor render obvious all the cumulative limitations of the claim with particular attention to the copolymer comprising about a 1:1 ratio of acrylamide and N,N-dimethylacrylamide.

Response to Arguments

22. Applicant's arguments filed 12-20-2007 have been fully considered but they are not persuasive. Applicant urges that Karger fails to disclose an active or deliberately cooled zone of the matrix coincident, but independent of, a stable and autonomous heated zone. Applicant further urges that Karger does not teach or employ the use of coexistent and autonomous zones specific to heating and cooling respectively. First, whether or not this is correct, the claims do not require this. All the claims call for is a deliberately cooled second portion and because Karger deliberately leaves the ends of the capillary outside of the denatured zone and because

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this would result in the second portion being cooled with respect to the heated portion by the exposure to ambient atmosphere, that would constitute a deliberate cooling of the capillary. The claims do not require independent, stable and/or autonomous zones. Second, this examiner has now included an alternative rejection over the teaching of Hjerten teaching that an independent, stable and/or autonomous cooling mean was an obvious modification of the teaching of Karger.

23. With respect to the rejections relying on Chu, this examiner agrees that Chu is not prior art against these claims and has withdrawn said rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
March 12, 2008